IN THE

Supreme Court of the United States

OCTOBER TERM, 1972

CASPAR W. WEINBERGER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE AND CHARLES C. EDWARDS, COMMISSIONER OF FOOD AND DRUGS, *Petitioners*

v.

HYNSON, WESTCOTT AND DUNNING, INCORPORATED

On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

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BRIEF FOR E. R. SQUIBB AND SONS, INC. AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

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No. 72-394

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INTEREST OF E. R. SQUIBB AND SONS, INC. AS AMICUS CURIAE

This brief amicus curiae in support of Hynson, Westcott and Dunning, Inc. (HW&D), is submitted by E. R. Squibb and Sons, Inc. (Squibb) pursuant to Rule 42 of the Rules of the Supreme Court of the United States.[1]

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[1] The written consent of petitioners and respondent have been lodged with the Clerk.

Squibb is a New Jersey corporation engaged in the manufacture and sale of pharmaceutical products. Squibb is presently engaged in litigation with the petitioners in a review proceeding involving an essentially identical legal issue to one which this Court may decide in this case (*E. R. Squibb and Sons, Inc.* v. *Secretary of Health, Education, and Welfare et al.*, No. 71-2138, presently pending in the United States Court of Appeals for the Third Circuit). The proceeding in which Squibb is a party was argued on January 19, 1973, at which time the Court of Appeals orally indicated an inclination to withhold its decision until this case is decided by this Court. Since the decision of this Court can be controlling on this issue in its case, Squibb has an interest in these proceedings and is submitting this brief amicus curiae.

This brief is limited to the issue of the validity of the procedures followed by the Food and Drug Administration in denying HW&D a hearing on the revocation of its new drug application for Lutrexin. We take no position as to the merits of the data and information which were submitted by HW&D in support of its request for hearing, or on the jurisdictional questions involved in whether HW&D is entitled to an administrative hearing on the new drug status of its product.

QUESTION PRESENTED

Whether, in an agency-instituted license revocation proceeding required by statute to be "after due notice and opportunity for hearing," the administrative agency may adopt a summary judgment procedure in which the license may be revoked without a hearing, without a finding or an evidentiary showing that there is no substantial issue of fact, and without an eviden-

tiary showing by the Agency on the record that the statutory grounds required for revocation exist. (J.A. 490-491)

STATUTORY PROVISIONS AND REGULATIONS INVOLVED

In addition to the provisions cited in petitioners' brief, the issue argued in this brief involves:

Section 7(c) of the Administrative Procedure Act (APA) (5 U.S.C. § 556(d)) which provides in pertinent part:

> § 556—Hearings; presiding employees; powers and duties; burden of proof; evidence; record as basis of decision.
>
> * * *
>
> (d) Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof. . . . A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence. A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form. . . .

The Fifth Amendment to the Constitution of the United States, which provides in pertinent part as follows:

> "No person shall be . . . deprived of life, liberty, or property without due process of law. . . ."

STATEMENT

On March 22, 1969 (prior to the promulgation of the procedural regulations involved in this proceeding) the Food and Drug Administration (FDA) published a Notice of Opportunity for Hearing on the proposed withdrawal of HW&D's license (new drug application) to market the drug Lutrexin in interstate commerce. (J.A. 12).[2] The notice alleged, as grounds for the withdrawal, in essentially statutory language, "that new information before the Commissioner with respect to such drugs evaluated together with the evidence available to him when the applications were approved shows there is a lack of substantial evidence of effectiveness of the drugs in that there is a lack of substantial evidence that lututrin, a component of [Lutrexin], has the effect or contributes to the effect which [Lutrexin] purport[s] or [is] represented to have under the conditions of use prescribed, recommended or suggested in the labeling thereof."

By letter dated April 18, 1969, HW&D requested that a hearing be held on the proposed withdrawal of these licenses. (J.A. 14)

On May 8, 1970, the Food and Drug Administration promulgated new procedural regulations purporting to condition the right to a hearing in license revocation proceedings of this type upon compliance with the requirement that the licensee, as a part of its request for a hearing, set forth a "well organized and full factual analysis of the clinical and other investigational data he is prepared to prove in support of his

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[2] J.A. refers to the Joint Appendix filed by the parties in this case and in Nos. 72-414, 72-528, 72-555, and 72-666, which have been consolidated with this case.

opposition to the notice of opportunity for hearing." According to the new regulations, the "request for hearing may not rest upon mere allegations or denials but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing." In the absence of such a showing the regulations permit the Commissioner to enter an order withdrawing the license without a hearing and without the presentation of any evidence by the Agency, 21 C.F.R. 130.14. (J.A. 490-491)

By letter dated May 19, 1970, eleven days after the promulgation of the new procedural regulations, the Commissioner wrote to HW&D demanding that it amend its request for hearing to comply with this new requirement. (J.A. 20)

HW&D at first refused to amend its request on the ground that the company was entitled to a hearing under the regulations in effect at the time the notice of opportunity for hearing was published. (J.A. 21) Subsequently, on October 16, 1970, HW&D did submit (1) a 4-page listing of data and information which it stated constitutes "substantial evidence," as defined in the May 8, 1970 regulations, thereby requiring that a hearing be held, and (2) seven affidavits (citing 11 studies), and other documents and correspondence in support of both its position that Lutrexin is not a "new drug," and the existence of "substantial evidence" requiring a hearing. (J.A. 24-32)

The Food and Drug Administration did not place into the record any evidence, data, information, affidavits, statements, or analysis of the material presented by HW&D, nor did it attempt to introduce or present any information to show the absence of any genuine

issue of fact in this proceeding. No such showing is required by the 130.14 procedural regulations.

On June 18, 1971, the Commissioner of Food and Drugs published a final order withdrawing approval of HW&D's new drug application for Lutrexin. The request for a hearing was denied "for failure to comply with applicable regulations." The 4-page listing of data and information which HW&D submitted as substantial evidence of effectiveness was dismissed on the grounds that:

> "What the Commissioner is required to do is determine from this material what HW&D may or may not consider relevant and, therefore, relies upon. In the case [of the] bibliographies, the Commissioner would be required to research each article and then determine if it is relevant, or whether HW&D might consider it relevant. Because such a procedure is not contemplated by the regulations, the request for a hearing is denied for failure to comply with applicable regulations." (J.A. 77)

There was no finding by the Commissioner that all of the data submitted or listed failed to show a "substantial issue of a material fact," nor could there have been such a finding since there was no examination of all the data listed.[3]

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[3] The statement from the Order quoted in petitioners' brief, at page 9, to the effect that in any event the material:

> " 'reveals a lack of adequate and well controlled investigations showing that lututrin will have the effect HW&D claims for it . . . ' "

appears to have been taken out of its context in the Order. In the Order, the quoted statement, by its own terms, specifically referred only to that portion of the data which had previously been included

On petition for review, the Court of Appeals held that HW&D is not entitled to a hearing on the issue of whether Lutrexin is a "new drug." This decision was based upon the lack of jurisdiction in the FDA administrative process to decide the issue. That portion of the decision is before the Court in Case No. 72-414.

The Court of Appeals also upheld the validity of the FDA's procedural regulations, but reversed the Commissioner's denial of a hearing on the ground that the data and information presented by HW&D, together with the Commissioner's objections to these data as they appeared in the Order, create "at most" a genuine

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"in the Lutrexin new drug application . . . ." (J.A. 78) The other listed data cited in support of the existence of substantial evidence, including the additional studies cited (see, J.A. 27-30), was not analyzed or discussed.

The "detailed review of Hynson's documentation" alleged by petitioners' brief at page 9, pertained only to that portion of the data which was cited in the affidavits submitted in support of HW&D claims that its product was not a "new drug." This review appears in the Commissioner's Order under the heading:

> "b. Lutrexin and Trexinest are new drugs within the meaning of 21 U.S.C. 321 (p)(1)." (J.A. 74)

No "detailed review" was presented under the heading:

> "c. The issue of substantial evidence of effectiveness, . . ." (J.A. 77)

with respect to the list of data submitted by HW&D on that issue (J.A. 27-30). To the extent that the data cited in the affidavits submitted to support "not new drug status" was also cited by HW&D in support of the existence of "substantial evidence," the analysis under "b" could, of course, have been utilized by the Commissioner under "c" for that portion of the "substantial evidence data." Even if that were done, however, there was still a substantial listing of data not reviewed "because" according to the Commissioner's Order, "such a procedure is not contemplated by the regulations." (J.A. 77-78)

issue of fact to be resolved at a hearing upon proper evidence. The petitioners in this case seek to have the Commissioner's Order reinstated.

The validity of the procedural regulations has been raised by HW&D as an alternate ground for affirmance, and argued by petitioners in their brief at pages 21-24.

ARGUMENT

I

INTRODUCTION

The Food and Drug Administration's procedural regulations involved in this proceeding (21 CFR 130.14) are, according to that agency, "an adaptation of the summary judgment procedures of the District Courts," 35 F.R. 7250, 7251 (May 8, 1970). Petitioners' brief, page 23, contends that "several other agencies currently have similar rules dispensing with a hearing when there is no genuine issue of fact to be determined."

However, all existing summary judgment procedures, whether administrative or judicial, other than the FDA's, incorporate the requirement that the moving party must show by documentary, admissible evidence that there is no genuine issue as to any material fact. Petitioners' regulations require no such showing by the FDA. Instead, they require the party defending against the "motion" to come forward with an initial, independent presentation of evidence establishing the existence of a genuine issue of fact in order to obtain a hearing. Under its regulations the FDA, by simply alleging in general statutory terms that a license should be revoked, thereby purports to shift the burden of

coming forward with proof both on the summary judgment motion, and on the issue of whether the license may be revoked, to the defending party.

Where, in a case such as this, the FDA decides that a licensee has not even complied with the requirement that evidence be presented,[4] the license may be revoked without the presentation of any evidence by the Commissioner.

It is precisely the absence of those safeguards embodied in both Rule 56 of the Federal Rules of Civil Procedure and the administrative summary decision rules and practices cited by the petitioner, but deliberately omitted from FDA's procedural regulations § 130.14, which cause the latter regulations to be, in the words of the Court of Appeals for the District of Columbia, "fundamentally defective,"[5] and violative of

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[4] The FDA has applied these regulations to deny a hearing in every new drug application license revocation since the promulgation of these regulations. The factual settings of these denials have varied from cases where no data was submitted in support of the request for hearing or analyzed in the final order, e.g., *USV Pharmaceutical Corp.* v. *Secretary of Health, Education and Welfare*, 466 F.2d 455 (C.A.D.C., 1972), where the Commissioner's Order was reversed; and *Ciba Geigy Corp.* v. *Richardson*, 446 F.2d 466 (C.A. 2, 1971), where the Commissioner's Order was upheld; to cases where data was submitted and an analysis of that data was contained in the final order, e.g., *Upjohn Co.* v. *Finch*, 422 F.2d 944 (C.A. 6, 1970), where the Commissioner's Order was upheld; and *E. R. Squibb and Sons, Inc.* v. *Richardson*, No. 71-2138 (C.A. 3), where affidavits were also submitted to establish that the data submitted constitutes "substantial evidence," this case is pending.

[5] *USV Pharmaceutical Corp.* v. *Secretary of Health, Education and Welfare*, 466 F.2d 455 (C.A.D.C. 1972). Although decided on August 14, 1972, before certiorari was allowed in these consolidated cases, the government did not petition this Court for certiorari in that case.

the requirements of the Federal Food, Drug, and Cosmetic Act (the Act), the Administrative Procedure Act (APA), and procedural due process.[6]

II

AS APPLIED IN THIS CASE, PETITIONERS' "SUMMARY JUDGMENT" REGULATION VIOLATES BOTH CONSTITUTIONAL AND STATUTORY REQUIREMENTS

Congressional delegation of quasi-judicial functions to administrative agencies has not relieved those agencies of compliance with fundamental due process requirements. *Ohio Bell Tel. Co.* v. *Public Utilities Commission,* 301 U.S. 292, 304; *Morgan* v. *United States,* 304 U.S. 1, 15-19. *See also, Final Report of the Attorney General's Committee on Administrative Procedures,* Senate Document No. 8, 77th Cong., 1st Sess., p. 62 (1941). In addition, Congress has itself prescribed both general and specific procedural requirements which these administrative agencies must follow in carrying out their limited assigned functions. The petitioners' May 8th hearing regulations, 21 C.F.R. 130.14, on the basis of which HW&D was denied its right to a hearing in this proceeding, as applied in this proceeding, violate both these constitutional and statutory limits.

This is not to say that a hearing would be required on applications where the application or request for a

[6] Even if due process and the Administrative Procedure Act did not require a full fair hearing including the proper allocation of the burden of proof, the Federal Food, Drug, and Cosmetic Act itself requires that an order withdrawing a New Drug Application "shall state the findings on which it is based," § 505(e), 21 U.S.C. 355(e), (J.A. 480) and that on appeal those findings of fact must be "supported by substantial evidence," section 505(h), 21 U.S.C. 355(h) (J.A. 480). The license cannot be withdrawn without any evidentiary showing by the Commissioner.

hearing does not "state a valid basis for a hearing," *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192; *Federal Power Commission* v. *Texaco, Inc.*, 377 U.S. 33. Administrative procedures may include the equivalent of motions under Rule 12 of the Federal Rules of Civil Procedure to dismiss for failure to state legal grounds upon which relief can be granted, or for judgment on the pleadings. This principle is not, however, pertinent to the present case since the Commissioner has not alleged the legal inadequacy of the allegations made by HW&D in its request for a hearing. Rather, he has refused to hold a hearing on the ground that HW&D allegedly failed to comply with the requirements of 21 C.F.R. 130.14 by presenting what the Commissioner will accept as a "well-organized" analysis of adequate supporting evidence showing the existence of a material issue of fact.

Further, Squibb does not contend that the mere allegation of adequate legal grounds must, in all cases, entitle a party to an evidentiary administrative hearing, any more than legally adequate pleadings necessarily entitle a litigant in a District Court to a trial. Administrative agencies should not be expected to waste their time on hearings where it can be shown that there is no genuine or material issue of fact. Unless prohibited by statute, rules for administrative summary judgment, with proper observance of required statutory and constitutional safeguards, may be adopted for this purpose. These principles are not disputed by Squibb in this case.

What is in dispute is whether the procedures followed here have been adequate to meet basic statutory and constitutional requirements.

A. Burden of Proof

Section 7(c) of the APA (5 U.S.C. § 556(d)), which is applicable to these proceedings, provides that "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." Both logic and the legislative history of the APA require that the "burden of proof" be construed to include the "burden of coming forward with a prima facie case." Thus, in discussing the effect of proposed section 7(c), the Senate Report states, "[t]hat the proponent of a rule or order has the burden of proof means . . . that the party initiating the proceeding has the general burden of coming forward with a prima facie case." Sen. Doc. No. 245, 79th Cong., 2d Sess., 208, 270 (1946). In this case, the Commissioner is the party who initiated the proceedings withdrawing approval of HW&D's new drug application and, accordingly, the burden of coming forward with a *prima facie* case rests squarely upon his shoulders.

The allocation of the burden of proof upon the Commissioner is not only required by the clear and unambiguous language of the APA but is well supported by case law. The Courts of Appeals have insisted that where an agency is the proponent of an Order in an adjudicatory proceeding, it cannot require the party who denies the validity or propriety of that Order to show cause why the Order should not be effectuated. See, e.g., *Saltzman* v. *Stromberg Carlson Telephone Manufacturing Co.,* 46 F.2d 612 (C.A.D.C., 1931); *Philadelphia Co.* v. *Securities and Exchange Commission,* 175 F.2d 808 (C.A.D.C., 1948), vacated as moot, 337 U.S. 901.

Despite petitioners' claim that ". . . every Court that has ruled on the question . . . has upheld the lawfulness

of the Commissioner's regulations . . . ," the fact is that the only Court of Appeals which has discussed or analyzed the issues involved in the allocation of the burden of proof under these regulations, has held "the procedures followed by the Commissioner were fundamentally defective." *USV Pharmaceutical Corp.* v. *Secretary of Health, Education, and Welfare,* 466 F.2d 455 (C.A.D.C., 1972). That case, in a proceeding essentially identical to this, held that it is incumbent upon the Commissioner, "before calling upon the [licensee] for additional evidence establishing a right to a hearing, to state facts and reasons showing at least prima facie that the evidence before him raised no material issue of fact which would justify a hearing . . . . Before calling upon the [licensee] to answer, the Commissioner, as the moving party, had an obligation to present at least a *prima facie* case for denial of a hearing." (*USV Pharmaceutical Corp* v. *Secretary of Health, Education, and Welfare, supra,* at p. 461) The court in that case reversed the Commissioner's Order withdrawing USV's license without a hearing.[7]

It is the Commissioner who is the proponent of the "Order" withdrawing approval of the new drug application, and it is HW&D who opposes the Order. It is the Commissioner who, by issuing the "Order" of revocation, has assumed the burden of establishing the propriety of the Order. It is up to him to prove the existence of the statutory criteria for withdrawal of new drug applications. He "may not by accusing put

[7] The cases cited by petitioners (Brief p. 24) do, of course, uphold the suspension of licenses pursuant to these regulations. All, however, preceded the *USV* decision, and none discussed the burden of proof issue which was held to be controlling in that case.

the accused upon proof." *Magnolia Petroleum Co.* v. *National Labor Relations Board,* 112 F.2d 545, 548 (C.A. 5, 1940).

It has long been firmly established that administrative hearings, especially in adjudicatory settings, are required to conform to all "the rudiments of fair play . . . assured to every litigant by [due process] as a minimal requirement, ..." As stated by Justice Cardozo in *Ohio Bell Tel. Co.* v. *Public Utilities Commission,* 301 U.S. 292 at 304:

> "Regulatory commissions have been invested with broad powers within the sphere of duty assigned to them by law. Even in quasi-judicial proceedings their informed and expert judgment exacts and receives a proper deference from courts when it has been reached with due submission to constitutional restraints. *West Ohio Gas Co.* v. *Public Utilities Comm'n* (No. 1), *supra,* p. 70; *West Ohio Gas Co.* v. *Public Utilities Comm'n* (No. 2), 294 U.S. 79; *Los Angeles Gas & Electric Corp.* v. *Railroad Commission,* 289 U.S. 287, 304. Indeed, much that they do within the realm of administrative discretion is exempt from supervision if those restraints have been obeyed. All the more insistent is the need, when power has been bestowed so freely, that the 'inexorable safeguard' (*St. Joseph Stock Yards Co.* v. *United States,* 298 U.S. 38, 72) of a fair and open hearing be maintained in its integrity. *Morgan* v. *United States,* 298 U.S. 468, 480, 481; *Interstate Commerce Comm'n* v. *Louisville & N.R. Co., supra.* The right to such a hearing is one of 'the rudiments of fair play' (*Chicago, M. & St. P. Ry. Co.* v. *Polt,* 232 U.S. 165, 168) assured to every litigant by the Fourteenth Amendment as a minimal requirement. *West Ohio Gas Co.* v. *Public Utilities Comm'n* (No. 1), (No. 2), *supra; Brinkerhoff-Faris Co.* v. *Hill,* 281 U.S. 673, 682. Cf. *Norwegian Nitrogen*

Co. v. *United States, supra.* There can be no compromise on the footing of convenience or expediency, or because of a natural desire to be rid of harassing delay, when that minimal requirement has been neglected or ignored." [8]

This principle has been followed and applied in a long line of cases to assure that litigants in administrative adjudications have adequate notice of the action to be taken and of issues to be tried, *Morgan* v. *United States,* 304 U.S. 1, 15-19; to require confrontation and cross-examination, *Greene* v. *McElroy,* 360 U.S. 474, 496-497, *Willner* v. *Committee on Character,* 373 U.S. 96, 103; to require that litigants be supplied with investigative reports supplied to the agency involved, *Gonzales* v. *United States,* 348 U.S. 407, 413-414, *Arndt* v. *United States,* 222 F.2d 484, 488 (C.A. 5, 1955); to require administrative regulations establishing standards for debarment (from participation in Commodity Credit Corporation contracts), and procedures which will include notice of specific charges, opportunity to present evidence and to cross-examine adverse witnesses, all

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[8] It is significant, in view of the petitioners' references to the burden of holding "hundreds or thousands" of pointless hearings (Brief p. 30, fn. 20, to note that the FDA does not now have any hearing examiners on its staff. The last resigned approximately two years ago. Despite its dire predictions of "hundreds or thousands" of hearings based upon the number of products reviewed by the NAS/NRC over the past five or six years, (Brief p. 19, and p. 22 of petitioners' brief in 72/555) petitioners have failed to suggest the one figure in its files which is pertinent to this problem—the number of hearings actually requested during that time.

We do not believe that the Federal Government cannot provide fair constitutional procedures without chaos. Certainly, the Agency should at least first attempt to handle the "problem" by the adoption of summary judgment procedures which conform to our traditional judicial and administrative concepts of "fair play."

culminating in administrative findings and conclusions based upon the record so made, *Gonzalez, et al.* v. *Freeman, et al.,* 334 F.2d 570 (C.A.D.C., 1964); to assure litigants of an unbiased and nonpartisan trier of fact, *NLRB* v. *Phelps,* 136 F.2d 562, 563 (C.A. 5, 1943); to safeguard "the minimal Constitutional requirement" that an agency must "receive and consider competent and material evidence offered by a party in a proceeding before it," *NLRB* v. *Air Associates,* 121 F.2d 586 (C.A. 2, 1941); and, to require that an agency which proposes to take action must assume the burden of proof in respect to the propriety of its proposed action, *Philadelphia Co.* v. *S.E.C.,* 175 F.2d 808 (C.A.D.C., 1948), vacated as moot, 337 U.S. 901; *Saltzman* v. *Stromberg Carlson Telephone Manufacturing Co.,* 46 F.2d 612 (C.A.D.C., 1931).

> "There are certain criteria of fairness in the hearing process which, in the absence of clear evidence of inapplicability in particular circumstances, should regularly be observed. Before adverse action is to be taken by an agency . . . the individual immediately concerned should be apprised not only of the contemplated action with sufficient precision to permit preparation to resist, but before final action, he should *be apprised of the evidence and contentions brought forward against him so that he may meet them* . . . These may properly be termed the *fundamentals ordinarily requisite to a fair hearing* leading to adverse action against an individual." (Emphasis added). *Final Report of the Attorney General's Committee on Administrative Procedure,* Senate Document No. 8, 77th Cong., 1st Sess., 62 (1941).

Conceptually, the Food and Drug Administration procedures violate these "rudiments of fair play" and

the statutory requirements of the APA, in two distinct ways: the administrative summary decision procedure does not require the FDA to show "the absence of a material issue of fact" in order to revoke the license without a hearing; and this and other cases have shown that as a result of the Commissioner's failure to present any evidence of his own, the orders issued in these cases violate the requirement that the Order be "on consideration of the whole record" and "supported by and in accordance with the reliable probative, and substantial evidence," section 7(c), Administrative Procedure Act, 5 U.S.C. 556(d), see also section 505(h), 21 U.S.C. 355(h). (J.A. 480)

(1) Commissioner's summary judgment procedure: failure to show absence of genuine issue of fact

The procedure followed by the Commissioner under his regulations appears to adopt the astonishing presumption that there is "no genuine and substantial issue of fact which precludes . . . the withdrawal of approval of the applications." For, if the request for a hearing by the holder of the license is deemed insufficient to establish such an issue, no hearing will be held. No showing need ever be made by the Commissioner to support his Order denying the hearing. In the present case, the state of the record is such that the Commissioner's denial of a hearing is based upon the allegation that HW&D "has not attempted compliance with [the procedural regulations]," (J.A. 77-78) and therefore has not carried his burden of establishing the existence of a factual issue. The Commissioner has not provided or attempted to provide evidence to affirmatively show the absence of a material issue of fact.

This distinction is, of course, basic to any fair adoption of a summary judgment procedure. A plaintiff is not entitled to summary judgment on the basis of a finding that the defendant has not shown the existence of a substantial issue of fact.

A fundamental principle on motion for summary judgment is that "the moving party . . . has the burden of showing the absence of a genuine issue as to any material fact" and that he is entitled to judgment as a matter of law, even though his opponent may have the burden of proving the facts at trial, *Adickes* v. *S. H. Kress and Co.,* 398 U.S. 144, 157.

Thus, it is Squibb's position that the Commissioner may not enter summary judgment in his own favor unless he first identifies and presents probative evidence of record sufficient to establish the absence of any such factual issues. He cannot merely rely upon a finding that the respondent has not affirmatively shown the existence of such an issue.

The Administrative Conference of the United States has, as indicated in petitioners' brief (P. Br. 23), suggested the adoption of a "Summary Decision Rule," by administrative agencies.[9] This proposed rule, however, provides for motions which may be granted if, but only if, the motion is supported by "pleadings, affidavits, material obtained by discovery or otherwise, or matters officially noticed" which show that there is no genuine issue as to any material fact. The burden is on the moving party to show the absence of any factual issues. If, but only if, such a motion "is made

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[9] 38 U.S.L. Week, 2658, June 9, 1970.

and supported as provided in this rule,"[10] the party opposing the motion is required to respond to establish a genuine issue of fact. By way of answer to the objection that summary judgment rules are not applicable to administrative hearings because "[t]he right to be heard means, at the least, the right of a party to present evidence and to test that offered by his adversary," the draftsmen of this model rule state:[11]

> "The short yet complete answer to these protests is that summary judgment is granted only when the papers filed with the motion clearly reveal that an evidentiary hearing would serve no useful purpose. Summary judgment honors the right to be heard by allowing the party opposing the motion to show the necessity for a trial *and by placing the burden on the party seeking summary disposition.*" (Emphasis supplied).

The petitioners' "summary judgment procedure" as applied in this case places no burden on the agency

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[10] It is not Squibb's contention that a prima facie case must include a showing by the Commissioner that the challenged drugs are ineffective or unsafe. Rather, it is Squibb's position that according to the explicit terms of § 505(e) of the Act the Commissioner must establish that the statutory criteria justifying revocation have been satisfied; i.e., he must come forward, identify and present probative evidence, including "new information" which "with the information available to him when the application was approved" establishes that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have . . . ." (J.A. 479).

[11] E. Gellhorn and W. F. Robinson, *Summary Judgment in Administrative Adjudication*, 84 Harv. L. Rev. 612, 616 (1971).

The proposed "Rule," set out in full in the cited article at page 628, is essentially identical to that which has been adopted by the F.T.C., 16 C.F.R. 3.24, (also cited by petitioners at p. 23 of their brief.)

when seeking summary disposition, but instead shifts the burden of coming forward with proof to the party opposing the motion, and provides for the granting of such an order against that party solely because he has failed to establish the existence of a factual issue. Such an Order, in a license revocation proceeding, clearly violates the APA, section 7(c), 5 U.S.C. § 556(d), due process requirements, and the requirements of the Federal Food, Drug, and Cosmetic Act that the license revocation must be based upon findings of fact and supported by substantial evidence. (§ 505(e) and (h), 21 U.S.C. 355(e) and (h)).

Petitioners appear to speak to this point in footnote 22, on page 32 of their brief, where in discussing *USV v. Secretary of Health, Education, and Welfare,* 466 F.2d 455 (C.A.D.C., 1972) it is contended that the Commissioner may, "by adopting the findings of the NAS/NRC panels rightly place upon the holder of NDA's issued prior to October 10, 1962 (when it was not necessary to submit any proof of effectiveness to receive approval of an NDA) the burden of coming forward with substantial evidence of effectiveness, to avoid withdraw of the approval of that NDA." The short answer to this *post hoc* argument by counsel in this Court is that the Notice of Opportunity for a Hearing in this case (J.A. 12) did not purport to adopt the NAS/NRC findings nor were they even referred to in the "Findings" made in support of the Order.[12] (J.A. 72-78). They did not because the 130.14 regulations under which the Order was issued are not designed for, or limited to, pre-1962 drugs or to situations where

[12] Nor, despite the quoted footnote, did the Commissioner "adopt" or even refer to the NAS/NRC review in the Notice, 33 F.R. 9908 (July 10, 1968), or in the Order, 35 F.R. 16332 (October 17, 1970), involved in the USV case.

NAS/NRC panels have spoken. The regulations provide for the same shift of the burden of coming forward with proof regardless of the vintage of the drug or the grounds alleged for withdrawal.[13] The NAS/NRC Panel review did not constitute any part of the Commissioner's "summary judgment" procedure under 21 C.F.R. 130.14, in this or any other proceeding.[14]

Petitioners' argument is therefore both *post hoc* and purely hypothetical, i.e., *had* the Commissioner adopted the findings of the NAS/NRC Panels, *then* he could have shifted the burden of coming forward with proof. Clearly the Order in this case was not based upon the panel reports because the Commissioner intended to

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[13] In addition to the grounds alleged in this proceeding, i.e.,— "new information . . . that there is a lack of substantial evidence . . ." of effectiveness, 21 U.S.C. 355(e) provides that a new drug application may be withdrawn if, e.g.,—

(1) the drug is "unsafe"

(2) new evidence shows that such drug is not shown to be safe

(3) the application contains any untrue statement of material fact

(4) the applicant fails to maintain certain records or make required reports

(5) on the basis of new information the labeling is false or misleading in any particular. (J.A. 479-480)

[14] The claim that the Notice had "adopted" the NAS/NRC findings was not briefed by either party in the Court of Appeals.

FDA has, in fact, applied these regulations in Notices of Opportunity for Hearing on Proposed Withdrawals of New Drug Applications involving only issues of "safety," and where there was no NAS/NRC, or any other committee opinion available to rely upon, see e.g., Notice of Opportunity for Hearing; Dienestrol Diacetate, 38 F.R. 3211 (February 2, 1973).

In other proceedings, the FDA has applied these regulations where the Order itself admits that the NAS/NRC conclusions were "unclear." Notice Withdrawing Approval of New Drug Applications, 36 F.R. 20543, 20545 (October 23, 1971).

base this Order (like the other Orders where there was no NAS/NRC review available) upon the far broader base of the procedural regulations which purport to automatically shift the burden of coming forward, with no showing of any kind.[15]

(2) Commissioner's final order; failure to present adequately supported findings

The Commissioner's final order in this proceeding must "state the findings on which it is based," 21 U.S.C. 355(e), and be "supported by and be in accordance with the reliable, probative and substantial evidence." 5 U.S.C. 556(d). The "burden of proof" of presenting sufficient probative evidence to support an order must be carried by the Commissioner and the findings must be based upon such evidence. However, under the procedures established by 130.14, no such showing or findings are required, nor were they made in this case.[16]

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[15] If the Court were to consider the argument that the Commissioner had inferentially attempted to adopt the NAS/NRC review as a basis for "shifting the burden of coming forward" we would be faced with the issues of (1) whether HW&D had proper notice of what arguments it was expected to meet on such a "summary judgment" motion, and (2) whether the unsworn, brief summary of views of a committee, which had, according to the summary itself, considered only two published papers (J.A. 7-10), would be sufficient to support a summary judgment decision. ("On summary judgment the inferences to be drawn from the underlying facts contained in such material must be viewed in the light most favorable to the party opposing the motion." *United States* v. *Diebold, Inc.*, 396 U.S. 654, 655.) However, since the Order does not purport to rely upon the Panel reports (nor did the petitioners' brief make this argument in the court below), this issue is not before this Court.

[16] This case was not unique in omitting findings of fact adequate to support either a summary administrative decision or the final order. Among the reported cases, no such findings were made in the orders rendered in *Ciba-Geigy Corp* v. *Richardson*, 446 F.2d 466 (C.A. 2, 1971), 35 F.R. 15253 (Sept. 30, 1970) or *USV Pharmaceutical Corp.* v. *Secretary of Health, Education, and Welfare*, 466 F.2d 455 (C.A.D.C., 1972), 35 F.R. 16332 (Oct. 17, 1970).

That part of the order which dealt with the alleged existence of "substantial evidence" was not and did not purport to be based upon an examination of all the data presented. Rather, the Order specifically recites the Commissioner's refusal to do so because according to the Commissioner, the "materials [relied upon by HW&D] are described for the most part in general terms (e.g., data presented in connection with the New Drug Application for Lutrexin tablets * * * Lutrexin bibliography * * * Trexinest bibliography * * * reprints and abstracts * * *)." The Commissioner specifically refused to "research each article and then determine if it is relevant . . . [b]ecause such a procedure is not contemplated by the regulations . . . ." (J.A. 77-78). Eleven studies were analyzed for the purpose of showing that "Lutrexin [is a] new drug within the meaning of 21 US.C. 321(p)(1)," (J.A. 74-77) and conclusionary general comments concerning what the Commissioner characterized only as "the most basic material in the Lutrexin new-drug application" were presented. (J.A. 78). It is, however, clear, and the Order does not allege otherwise, that these two categories do not exhaust the listing of information and data presented by HW&D in support of its position regarding the existence of "substantial evidence." [17]

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[17] Since this brief is limited to legal procedural issues, we have not attempted to argue whether the findings which were actually made concerning the eleven studies are in fact supported by the record. However, it is apparent that at least certain of the Commissioner's alleged reasons for dismissing these eleven studies were based upon evidence and information which is not in, or supported by, the record. For instance, the Commissioner's criticism (J.A. 75) of the statistical treatment of the Magewski study, "Statistical Evaluation of the Reduction of the Incidence of Prematurity (1968)" criticizes the manner in which the author presented his data concerning "24 [women] with one previous pregnancy" and suggests an alternative presentation. The author's presentation

The absence of adequate findings of fact "on consideration of the whole record" and "supported by and in accordance with reliable, probative, and substantial evidence," to support the Commissioner's conclusions, in statutory language "that on the basis of new information before him with respect to [Lutrexin] evaluated together with the evidence available to him when [such] application was approved, there is a lack of substantial evidence that [it] will have the effects it is purported to have . . ." violates section 7(c) of the Administrative Procedure Act, 5 U.S.C. 556(d), and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(e) and (h), see *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, *Labor Board* v. *Brown*, 380 U.S. 278, 291.

CONCLUSION

The Court of Appeals in this case upheld the validity of the Commissioner's regulations but reversed the order withdrawing the new drug application without a hearing on the ground that "the showing of [HW&D] was such that under a reasonable construction of the Commissioner's own regulations, as well as under

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(J.A. 110) appears to be for the purpose of evaluating the effectiveness of Lutrexin for increasing the likelihood of "live births" by these 24 women, as compared with their own prior experiences during their own prior pregnancies. The Commissioner's suggested alternative "paring" would result in a comparison of the "live birth" percentage in these 24 women during their second pregnancies, against the "live birth" percentage in 15 other women during their first and second pregnancies. Which of these comparisons is more meaningful is, at the very least, a question of fact requiring evidentiary support. Similarly, although the author analyzed the data in the same Table I by the "chi-square method," the Commissioner states that it "does not admit to a statistical evaluation by the chi-square method since the test is based on the assumption that each number of the columns in Table I is the sum of independent yes or no responses . . . ." (J.A. 75) Such a finding also requires, at the very least, a factual basis in expert testimony, subject to cross-examination and rebuttal by HW&D.

familiar principles of due process and the requirements of the Administrative Procedure Act, it was entitled to an impartial hearing before its NDA was withdrawn." (J.A. 179)

The petitioners have, in this case, sought review of that finding. Squibb recognizes that this Court may affirm the decision of the Court below for the reasons stated by the Court of Appeals—i.e., Hynson, Westcott and Dunning's showing was adequate to require a hearing even under the Commissioner's regulations—without the need to reach the question of whether the regulations are themselves valid. Indeed, this course may be preferable since the adequacy of that showing was the ground relied upon in the Court of Appeals. If this is done, however, the fact that the validity of the regulations has not been decided by this Court should be clearly stated so that the important questions of administrative law presented by these regulations, and potentially affecting administrative practices by all agencies, will not be foreclosed without adequate consideration by this Court.

On the other hand, if the Court should find that HW&D's showing was not adequate under the Commissioner's regulations, it must of necessity reach the issue of the validity of these regulations. On this issue, we submit that these regulations are invalid, and that the judgment of the Court of Appeals should be affirmed on that ground.

Respectfully submitted,

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